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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,246	07/11/2003	Gaston J. Levesque	814-042-3-2	4614

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WARE FRESSOLA VAN DER SLUYS &
ADOLPHSON, LLP
BRADFORD GREEN BUILDING 5
755 MAIN STREET, P O BOX 224
MONROE, CT 06468

EXAMINER	
DAWSON, GLENN K	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,246	LEVESQUE ET AL.	
	Examiner	Art Unit	
	Glenn K Dawson	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,6-34 and 39-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *40-44* is/are allowed.

6)☒ Claim(s) *1,3,6-34,39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: copy of 60/446725

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14 and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 14 and 39 claim a secondary distribution channel extending inwardly from the suction channel and intersecting the conduit opening. This is also consistent with the description on page 22 of the specification. However, the figures do not show the channel extending inwardly (toward the center of the aperture). The description is vague and unclear, especially in view of the figures. Clarification and correction is required.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the secondary channel extending inwardly from the suction channel must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

Claim1 and 7-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the phrase "a drive means access to the drive track" is vague and unclear. It is not clear if applicant is intending to invoke 112 6th with this language.

In claim 7, there is a double recitation of the sole surface which has already been recited in claim 6 line 3.

In claim 33, there is no antecedent basis for "the drive shaft of the cutter head" and "the cutting instrument motor".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Dybbs-6228099.

Dybbs discloses a keratomes having a suction ring 86, a cutting head having a holder 96 driven by a pin 147 and a shoe 76 having guideways 82 which receive bars on the cutter drive unit 94 for guiding the cutter back and forth. The entrance guideway is the proximal-most portion of the guides and the cutting guideway is the middle to distal-most portion of the guides. These portions are all axially aligned.

Dybbs is applied because, as evidenced by the attached copy of the provisional application to which Dybbs claims priority (60/066725), it discloses all of the above claimed limitations. However, applicant's prior applications filed before the filing date of 60/066725 do not disclose the claimed subject matter of claims 3 and 6 of the present application. If applicant provides evidence of support for the claimed invention prior to the 11-21-1997 date of the Dybbs application, then this rejection will be withdrawn.

Allowable Subject Matter

Claims 40-44 are allowed.

Claims 7-13 and 15-34 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 02-25-2005 have been fully considered but they are not persuasive.

As pointed out above, the Dybbs reference does predate applicant's effective filing date for the rejected claims 3 and 6. The entrance guideway of Dybbs is just an extension of the cutting guideway, which is consistent with the claim language.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K Dawson whose telephone number is 703-308-4304. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on 703-308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Glenn K Dawson
Primary Examiner
Art Unit 3731

Gkd
10 May 2005

AIPROV

EXPRESS MAIL LABEL NO. EI841743818US   DATE OF DEPOSIT NOVEMBER 21, 1997

Jc546 U.S. PTO 11/21/97

PROVISIONAL APPLICATION COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION under 37 CFR 1.53 (b)(2).

Docket Number	REFTP0101US		

INVENTOR(s)/APPLICANT(s)			
LAST NAME	FIRST NAME	M.I.	RESIDENCE (CITY AND STATE/COUNTRY)
Dybbs	Alexander		Cleveland, Ohio, USA

TITLE OF THE INVENTION

OPHTHALMIC SURGICAL SYSTEM AND METHOD

CORRESPONDENCE ADDRESS

Don W. Bulson, Esq.
Renner, Otto, Boisselle & Sklar, P.L.L
1621 Euclid Avenue, 19th Floor
Cleveland, Ohio 44115

Tel: 216-621-1113
Fax: 216-621-6165

ENCLOSED APPLICATION PARTS *(check all that apply)*

40 Pages of Specification   X Small Entity Statement
13 Sheets of Drawing(s)   ___ Other ______

METHOD OF PAYMENT *(check one)*

	Provisional Filing Fee Amount	
X Enclosed is check covering the filing fee* ___ Charge Deposit Account No. 18-0988		$75.00

*The Commissioner is authorized to charge any additional fee or credit overpayment to Dep. Acct. No. 18-0988.

60065725 . 112197

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

X No.

___ Yes, and the name of the U.S. Government agency and the Government contract number are: ______

Respectfully submitted,

Date: November 21, 1997

Christopher B. Jacobs

Christopher B. Jacobs, Reg. No. 37,853

___ Additional inventors are being named on separately numbered sheets

C:\G\CBJ\REFT\P0101US.P01.wpd/A-PR-CVR.FRM

RENNER, OTTO, BOISSELLE & SKLAR, P.L.L.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant or Patentee: Alexander Dybbs Attorney's Docket No. REPTP0101US
Serial or Patent No.
Filed or Issued:
For: OPHTHALMIC SURGICAL SYSTEM AND METHOD

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) and 1.27(b)) - INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled OPHTHALMIC SURGICAL SYSTEM AND METHOD and described in

[X] the specification filed herewith
[ ] application serial no. , filed
[ ] patent no. , issued

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

[ ] no such person, concern, or organization
[ ] persons, concerns or organizations listed in the Appendix hereto

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR
Alexander Dybbs		
Signature of Inventor	Signature of Inventor	Signature of Inventor
11/21/97		
Date	Date	Date

SB-0.FRM (4/92)

REFTP0101US

Title: **OPHTHALMIC SURGICAL SYSTEM AND METHOD**

FIELD OF THE INVENTION

The invention relates to an ophthalmic surgical system and method including a disposable surgical microkeratome and, more particularly, to a surgical system and method for using such a device in laser in situ keratomileusis (LASIK).

BACKGROUND OF THE INVENTION

In the past thirty-five years, several opthalmic surgical methods and devices have been developed and increasingly are used to change the shape of the cornea to correct vision defects, including myopia, hyperopia and astigmatism.

An early technique included a "primary keratectomy" in which an anterior corneal lenticle is removed by manually pushing a blade of a microkeratome across the cornea. Then a "refractive keratectomy" is performed, wherein an optic correction is carved in the surface of the lenticle with a lathe similar to a contact lens lathe. The lenticle is sutured back in place on the eye. When an even and smooth cut is achieved, the best and most predictable results are obtained. However, the manual microkeratomes are difficult to use and require some skill to propel the blade across the cornea in an even and smooth manner, thereby providing varying qualities of primary keratectomies based on the skill and experience of the surgeon. As a result, the predictability of the refractive correction was minimal.

The methods and devices have evolved over the years to an automated, mechanical movement of the microkeratome blade across the cornea which provides a steady, even cut which improves the predictability of the refractive correction. Furthermore, the lenticle is not completely severed from the cornea. Instead a flap is cut from the cornea, the back of the flap or the exposed stromal bed is sculpted in situ with an excimer laser to provide the refractive correction, and the flap is replaced without sutures. This procedure is called laser in situ keratomileusis (LASIK). LASIK greatly improves the predictability of the amount of change in refractive correction and greatly reduces the amount of time required for the cornea to heal. In addition, the patient experiences a relative lack of discomfort from this procedure.

Unfortunately, problems still remain with some microkeratomes used to make the flap. Some existing microkeratomes still require the surgeon to estimate the length of the cut to make the flap because the cutting distance is not automated. Generally microkeratomes are made of surgical steel which prevents the surgeon from viewing the cornea as the cutting blade oscillates and advances.

Another problem with some microkeratomes is that they are made of many small metal components which are expensive to produce and assemble. The assembled microkeratome may be less than two inches long, and individual components may be much smaller. As a result, cleaning and sterilization of the microkeratome between patients is very difficult. Sometimes the microkeratome must be at least partially

disassembled and each component cleaned by hand. Therefore, the existing microkeratomes are difficult or even impossible to maintain in an acceptably sterile condition. Additionally, as one might imagine the assembly of many small parts while wearing sterile gloves is very difficult.

Some existing microkeratomes have one or more of the following problems in addition to those described above. For example, on some microkeratomes the depth of cut is determined by an adjustment plate which must be selected and added to the parts assembled before the operation. A last minute change may require the microkeratome to be disassembled, the adjustment plate changed, and then reassembled. Another problem is that some microkeratomes use a mechanical stop to halt the advance of the cutting blade, thereby stalling the motor. This damages the motor and reduces its useful life. Furthermore, some microkeratomes are relatively heavy, thus placing undue pressure on the eye and hindering precise location on the eye. Yet another problem with some microkeratomes is that a base must be attached to the eye and then a cutting device must be assembled and/or mounted thereon.

A microkeratome which is easy to use, disposable or easy to clean, and performs a keratectomy in a consistent, smooth and reliable manner would be desirable.

SUMMARY OF THE INVENTION

The present invention provides an opthalmic surgical system and method including a microkeratome that overcomes the problems of the prior art. The present invention provides independent control of the oscillation and the linear advancement and retraction of a cutting blade to provide a consistently high quality lamellar flap in the cornea of an eye. In addition, a control assembly that powers and controls a movement of the cutting blade is able to be remote from the microkeratome. This alows the microkeratome to be pre-assemblable, sterilizable, and preferably disposable. Furthermore, the microkeratome of the present invention preferably is made of a clear plastic, making the microkeratome lightweight, easy to produce and use, while allowing the surgeon to observe the cornea as the blade advances.

The present invention, in particular, provides a system for keratomileusis opthalmic surgery which comprises a microkeratome and a control assembly. In a preferred embodiment, the microkeratome includes a suction platform and a cutting assembly on the suction platform. The suction platform in the base thereof an opening therethrough to a suction chamber at the underside of the suction platform. The suction chamber is adapted to be seated on an eye such that at least a portion of a cornea of the eye extends through the opening. The cutting assembly has a cutting blade carried in a carriage that is movable in a linear direction across the opening in the top surface of the suction platform. The control assembly includes an axial drive for generating linear movement. The axial drive is connected to the microkeratome to impart linear

movement in a cutting direction to the cutting assembly relative to the suction platform. The control assembly also includes a rotary drive for generating rotational movement and the roatry drive is connected to the microkeratome to impart an oscillating movement to the cutting blade transverse to the cutting direction. The control assembly also includes a suction device for generating a partial vacuum which is connected to the microkeratome. The suction device generates a partial vacuum in the suction chamber to maintain a position of the suction platform relative to the eye. The control assembly also includes a controller for independently controlling the axial drive and the rotary drive.

According to a preferred embodiment of the present invention, substantially every part of the microkeratome is formed of a substantially transparent material.

According to another preferred embodiment of the present invention, the control assembly includes a drive assembly. The drive assembly includes the axial drive, a slide member connected to the axial drive, and the rotary drive. The slide member is moved through a range of linear motion by the axial drive and the rotary drive is mounted on the slide member for movement therewith. Furthermore, the axial drive is connected to the microkeratome through an axial shaft connected to the slide member; and the rotary drive is connected to the microkeratome through a rotary shaft. The suction device can include a suction pump which is connected to the suction platform of the microkeratome through a suction tube.

The cutting assembly includes a cutting head, a blade holder, the cutting blade and a wedge. The cutting head has an angled bottom surface with a transverse slot opening thereto, at least one recess therein and a back surface with a passage extending therethrough to the transverse slot. The blade holder has a protrusion on a bottom end thereof and a vertical slot in a side of the blade holder. The blade holder is received in the transverse slot for transverse movement therein with the protrusion extending below the bottom surface of the cutting head. The cutting blade has a cutting edge and a central opening. The protrusion on the blade holder engages the central opening in the cutting blade for moving the cutting blade transversely with the blade holder. The wedge has an angled top surface substantially parallel to the angled bottom surface of the cutting head. The wedge also has at least one protrusion extending from the angled top surface to engage the recess or recesses in the cutting head and hold the wedge against the cutting head and retain the blade holder and blade in the cutting assembly.

The rotary shaft has an eccentric on an end thereof which communicates with the vertical slot in the blade holder and cooperates therewith to convert the rotational motion of the rotary shaft into a transverse oscillating motion of the cutting blade. The axial shaft is connected to the back side of the wedge to move the cutting assembly across the suction platform.

The transverse slot in the cutting head is perpendicular to the angled bottom surface of the cutting head and the passage through the cutting head is parallel to the angled bottom surface.

According to one embodiment of the invention, The rotary shaft is connected to the cutting assembly with a bayonet coupling. The microkeratome also has an axial retaining clip mounted on the suction platform, for holding a fitting on the end of the axial cable. The axial shaft passes through the fitting and is attached to the cutting assembly.

According to one embodiment of the invention, the axial shaft is connected to the cutting assembly with a T-pin that engages a slot in the back side of the wedge.

The microkeratome according to the present invention may further include at least one guide on the surface of the suction platform for retaining the cutting assembly adjacent the suction platform and for directing the motion of the cutting assembly across the suction platform. In addition, the suction chamber on the suction platform forms a hollow cylinder which aligned with the opening in the suction platform for passage of a portion of an eye therethrough. A suction pipe is attached to the suction platform in line with the direction of motion of the cutting assembly and is adapted to connect the suction chamber with a suction device.

A method for keratomileusis opthalmic surgery according to the present invention provides independent control of the movement of a cutting blade in a linear direction

and in a transverse direction. The method comprises the steps of advancing a cutting blade from an initial position in the linear direction while simultaneously moving the blade in a direction transverse the linear direction; stopping the linear advance and transverse motion of the blade at a hinge position which is a predetermined distance from the initial position; and linearly retracting the blade to the initial position without imparting transverse motion to the blade.

The method may further comprise the steps of connecting an axial drive to the cutting assembly to advance and retract the cutting blade; connecting a rotary drive to a cutting assembly to oscillate the cutting blade; applying a microkeratome containing the cutting assembly to an eye; and retaining the position of the cutting assembly relative to the eye with a suction device creating a partial vacuum between the microkeratome and the eye.

According to one aspect of the invention, the stopping step includes stopping the linear advance of the blade at an end position which is a less than three quarters of the distance across the eye.

The method may further comprise the steps of stopping the axial drive and the rotary drive when a suction pressure is reduced below a predetermined value.

The foregoing and other features of the invention are hereinafter fully described and particularly pointed out in the claims, the following description and annexed drawings setting forth in detail a certain illustrative embodiment of the invention, this

embodiment being indicative, however, of but one of the various ways in which the principles of the invention may be employed.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic view of the opthalmic surgical system according to the present invention.

Fig. 2 is a side view of a flap length adjustment selector according to the present invention shown in a cutaway view of the control assembly housing.

Fig. 3 is an exploded perspective view of the microkeratome according to the present invention looking down toward the top and one side of the suction platform.

Fig. 4 is an exploded perspective view of the microkeratome according to the present invention as seen from below the suction platform.

Fig. 5 is a perspective view of the suction platform.

Fig. 6 is a perspective view of the top of the cutting head.

Fig. 7 is a bottom perspective view of the cutting head.

Fig. 8 is a perspective view of the blade holder.

Fig. 9 is a perspective view of the wedge.

Fig. 10 is a perspective view of the axial retaining clip.

Fig. 11 is a perspective view of the microkeratome in a first position showing the connections of the control cables and the suction tube.

Fig. 12 is a perspective view of the microkeratome in a second position.

Fig. 13 is a schematic of the control system according to the present invention.

DETAILED DESCRIPTION

The present invention includes a system and method using a disposable microkeratome 12 that facilitates the performance of corrective refractive opthalmic surgery, particularly keratomileusis, and more particularly laser in situ keratomileusis, LASIK, with independent control of a transverse oscillating motion, an advancing motion, and a retracting motion of a cutting blade.

Referring now to the drawings in detail and initially to Fig. 1, a preferred embodiment of the ophthalmic surgical system 10 including a disposable surgical microkeratome 12 according to the present invention is shown.

In addition to the disposable microkeratome 12, the system 10 includes a control assembly 14, a flexible suction line or tube 16, and a pair of flexible control cables 18 and 20. The suction line 16 and control cables 18 and 20 are connected between the control assembly 14 and the microkeratome 12 so as to remotely control and drive the microkeratome 12. The control assembly 14 includes control and driving components of the system 10. These components are more expensive to produce and are intended to be reused for surgery on many patients. The control assembly 14 is removed from the surgical area and generally avoids any contact with the patient, thereby improving sterilization of the control and the driving components of the system.

The microkeratome 12, which comes into direct contact with the patient, may be used on a single eye or a pair of eyes on a single patient and then may be disposed. Since the microkeratome 12 according the present invention is simply designed and easily produced it is disposable and cheaply replaced. No assembly of the microkeratome 12 is required by the surgical staff. The microkeratome can be provided completely assembled, sterilized and ready for use. Since the microkeratome 12 comes into contact with the eye, and since the small components of the microkeratome 12 do not require cleaning and sterilizing, the system 10 is easier and more effectively maintained in a clean and sterile condition.

An exemplary embodiment of the present invention includes the microkeratome 12 and the control assembly 14 shown in the figures. As illustrated in Fig. 1, the control assembly 14 is contained within a housing 22 and includes a drive assembly 24, a suction pump 26, and a controller 28 which controls the operation of the drive assembly 24 and the pump 26. The controller 28 preferably includes an electronic circuit connected to and communicating with the components of the control assembly 14. The control assembly 14 also has several input devices, including an ON/OFF switch 30, a one-position suction pedal or switch 31, a two-position foot pedal or switch 32 and a flap length adjustment selector 34, also called a hinge positioning system. The input devices permit the surgeon to control several variables in the operation of the system 10, as further described below.

Because each eye is a different size and has a different curvature, the position of the hinge or the length of the flap is desirably selected by the flap length adjustment selector 34 prior to operation of the system. As shown in Fig. 2, the flap length adjustment selector 34 includes a substantially disk shaped stepped cam device 36 having a stepped edge surface. The cam 36 is supported for rotation about a pivot axle 38 by a pair of support arms 40 (one shown). Although the stepped cam 36 is part of the preferred embodiment for selecting the desired cutting length, other types of input devices may be used, including but not limited to a dial indicator, a pushbutton selector, an electronic keypad, or microcomputer input devices such as a keyboard, liquid crystal display and mouse.

A control arm 42 is connected to the cam 36 and extends through the housing 22 for rotating the cam to various positions. The flap length adjustment selector 34 includes a flap length microswitch 44. The flap length microswitch 44 includes a microswitch arm 46 which is biased against the cam 36 for sensing the position of the cam. The microswitch 44 provides a signal to the controller (not shown) which indicates the desired cutting length. The controller 28 (Fig. 1) uses the desired cutting length indicated by the flap length adjustment selector 34 to control the drive assembly 24 to create a flap of sufficient size without completely severing a section from the cornea, preferably cutting a flap having a uniform thickness and a length of about three-quarters of the distance across a cornea, about nine to twelve millimeters.

Each step in the surface of the cam has a rounded base leading to an adjacent step. The rounded bases of the steps on the cam 36 minimize or prevent the microswitch arm 46 from catching between the steps, encouraging the microswitch arm to roll up and over each step as the cam rotates.

Returning to Fig. 1, the drive assembly 24 includes a linear motor 50 which is connected to a slide member 52, for example by rack and pinion gears 54 and 56, respectively, for moving the slide member 52 through a range of linear motion corresponding to the desired cut length. An initial position microswitch 68 and a hinge position microswitch 70 are located at opposing ends of the range of motion for the slide member 52. These microswitches 68 and 70 are connected to the controller 28 to signal the presence of the slide member 52 at either microswitch 68 and 70.

A rotary motor 60 is mounted on the slide member 52 for movement therewith. The slide member 52 is mounted on a pair of parallel rods 62 which act as slide guides for directing or guiding the motion of the slide member 52 in a linear direction. An axial shaft 64 is connected to the slide member 52 for translating the linear motion of the slide member 52 to the microkeratome 12 and a rotary shaft 66 is connected to the rotary motor 60 for transferring rotational motion to the microkeratome 12. Because the rotary motor 60 is mounted on the slide member 52, the rotary shaft 66 also moves in a linear direction with the slide member 52. Therefore, both the axial shaft 64 and the rotary shaft 66 advance and retract with the slide member 52.

The flexible shafts 64 and 66 described above are of special construction. The rotary shaft 66 has a monocoil, double wound or triple wound construction over a central wire or mandrel. The winds are pitched in opposite directions to provide torsional rigidity. The rotary shaft is preferably made of stainless steel wire due to its greater strength and endurance limit and, more preferably, the shaft is made of 302 stainless steel. The triple wound construction provides better bi-directional properties as well as greater flexibility needed to increase the endurance life of the shaft, compared to a monocoil or double wound construction. The torsional stiffness, however, is equivalent to or greater than the double wound construction but its flexural stiffness is less than half that of the double wound construction. This is necessary since the shaft rotates in a relatively sharp bend, at high speed. Furthermore, the rotary shaft 66 is coated with a very thin wall shrink tubing in order to provide a smooth surface to minimize or eliminate vibration. Thus, the rotary shaft is designed to rotate at speeds up to twenty thousand revolutions per minute and to provide the necessary torque to oscillate a cutting blade (not shown) in the microkeratome 12.

The axial shaft 64 is preferably double wound over a central wire or mandrel. The winds are pitched in opposite directions to provide some torsional rigidity. The pitch angles, or helix angles, are preferably less than forty degrees to make the shaft more flexible than a traditional push-pull cable. However, the central mandrel or wire is larger in diameter than the wires in the outer layers to increase axial and flexural

rigidity. This combination provides optimum flexibility without sacrificing "pushability" or the ability to transmit a pushing force from the axial motor 50 to the microkeratome 12.

Both the axial and rotary shafts 64 and 66 are encased in flexible jackets, sheathings or casings, that permit the shafts to move axially therein. The rotary and axial shafts 66 and 64 and jackets form a rotary cable 18 and an axial cable 20, respectively. The rotary cable 18 and the axial cable 20 connect the rotary motor 60 and the axial motor 50, respectively, to the microkeratome 12. Both the axial shaft 64 and the rotary shaft 66 move through the cables 20 and 18, respectively, as the slide member 52 moves through its range of motion and move forward and backward with the cutting assembly relative to the suction platform. Preferably, the inside of the cables are coated with a material to reduce friction between the jackets and the cables, for example polytetrafluoroethylene (PTFE).

Figs. 3 and 4 show exploded perspective views of the microkeratome 12 and its components. The microkeratome 12 includes two main subassemblies, a suction platform assembly 72 and a cutting assembly 74. The suction platform assembly 72 locates and attaches to the eye and the cutting assembly 74 moves in a linear direction across the suction platform assembly 72 to cut the flap in the cornea.

The suction platform assembly 72 includes a suction platform 76 and a substantially C shaped anchor or axial retaining clip 78. The suction platform 76, shown in Figs. 4 and 5, has a substantially flat and substantially rectangular top surface

80 which supports the cutting assembly 74. Parallel to the longer sides of the rectangular top surface 80, the suction platform 76 includes a pair of platform guides 82 which oppose each other and form a track which restrains and guides the cutting assembly 74 along the suction platform 76. The track functions to restrain and guide the cutting assembly 74 such that the cutting assembly 74 can only move forward and backward in a linear direction parallel to the length of the platform guides 82. The track also functions to hold the cutting assembly 74 on the surface of the suction platform 76 such that the cutting assembly 74 cannot move in a direction perpendicular from the top surface 80 of the suction platform 76.

At a back end of the suction platform 76, the suction platform has a slot 144 which engages the retaining clip 78. The shape of the base of the retaining clip 78 and the shape of the slot 144 cooperate to slidingly engage one another to retain the retaining clip 144 on the suction platform 76. The retaining clip 78 also retains the cutting assembly 74 between the platform guides 82 and prevents the cutting assembly from disengaging the platform guides 82. The retaining clip 78 also functions to anchor the axial cable 20 relative to the suction platform assembly 72 by engaging a groove in a fitting 146 on an end of the axial cable 20.

At one end of the suction platform 76 and interposed between the platform guides 82, the top surface 80 has a circular opening 84. The cutting assembly 74 moves in a forward direction toward and across a portion of the circular opening 84 and

in a reverse direction back across and away from the circular opening 84. The circular opening 84 provides a sufficiently large aperture size to cut flaps in hyperopia. The opening 84 communicates through the top surface 80 of the suction platform 76 to a substantially cylindrical suction chamber 86.

The suction chamber 86 includes a cylindrical suction ring 88 which is larger than the circular opening 84 in the suction platform 76. The suction ring 88 and suction platform 76 cooperate with the surface of an eye to form the suction chamber 86 therebetween. A bottom inside surface of the suction ring 88 is beveled to improve the seal with the eye. In addition, the suction chamber 86 may include at its bottom surface thereof a material, coating or sealant for improving the contact with the eye and maintaining the partial vacuum between the suction chamber 86 and an eye. The sealant may include a silicone.

From the suction chamber 86 and adjacent the inner circumference of the suction ring 88, a suction pipe 90 extends above the top surface 80 of the suction platform 76. The suction chamber 90 communicates through the suction pipe 90 to a suction line 16 (Fig. 1) which in turn is connected to the suction pump 26 (Fig. 1) for providing suction to the suction chamber 86.

The suction is applied to the suction chamber 86 through the suction pipe 90 to create a partial vacuum in the suction chamber 86. The partial vacuum retains the suction platform 76 in a stable position relative to the eye for operation thereon. The

suction pump 26 (Fig. 1) creates suction in such a way that when the suction platform 76 adheres to the cornea, the intraocular pressure in the eye is raised to and maintained at at least about sixty millimeters of mercury. In addition, when suction is applied to the suction chamber 86, the cornea protrudes through the circular opening 84 in the suction platform 76. Preferably the suction pipe 90 is in line with the direction of motion of the cutting assembly to provide an unobstructed view of the cornea.

As illustrated in Figs. 3 and 4, the cutting assembly 74 includes a cutting head 84, a blade holder 96, a cutting blade 98, and a wedge 100.

Figs. 6 and 7 show top and bottom perspective views of the cutting head 94 respectively. The cutting head 94 includes a forward sled 110 at a forward end of the cutting assembly 74 (Fig. 3). The sled 110 forms a shelf which is interposed between a pair of rails 112 which extend from the sides of the cutting head 94. The rails 112 are parallel to and slidingly engage the platform guides 82 (Fig. 5) on the suction platform 76 (see Fig. 5). As the cutting assembly 74 (Fig. 3) moves across the circular opening 84 (Fig. 4), a bottom surface of the sled 110 flattens the surface of the eye.

Behind the sled 110 the cutting head 94 also includes the angled blade surface 104 on the underside of the cutting head 94. The blade surface 104 is angled relative to the top surface 80 of the suction platform 76 such that a forward edge of the blade surface 104 is closer to the suction platform 76 than a rear edge of the blade surface.

Substantially perpendicular to the angled surface 104 and opening toward the angled surface 104, the cutting head 94 has a transverse slot 114 for slidingly receiving the blade holder 96 (Fig. 3) therein. The transverse slot 114 is wider in a transverse direction than the blade holder 96 (Fig. 3), thereby permitting the blade holder 96 (Fig. 3) to oscillate within the slot 114. The width of the slot is transverse to the direction of motion of the cutting head 94. The transverse oscillation of the blade holder 96 creates a transverse oscillation of the cutting blade 98.

The cutting blade 98, shown in Figs. 3 and 4, has a cutting edge 102 which preferably is held at an angle transverse to the direction of motion of the cutting assembly 74, and more preferably at an angle of at least twenty-six degrees relative to the forward direction. The cutting blade 98 is held at an angle to the surface 80 of the suction platform 76 between the angled blade surface 104 of the cutting head 94 and a parallel angled top surface 106 of the wedge 100. The cutting edge 102 and the cutting blade 98 may be held at other angles, however, relative to the top surface 80 and/or the direction of motion.

The cutting blade 98 extends the cutting edge 102 beyond the angled surface 104 between the cutting head 94 and the surface 80 of the suction platform 76. The distance between the cutting edge 102 (Fig. 3) and a bottom surface of the sled 110 forms a blade gap distance. The blade gap distance determines the thickness of the flap, preferably about one hundred fifty to one hundred sixty micrometers.

Figs. 4 and 8 illustrate the blade holder 96 which has a protrusion 120 that protrudes beyond the transverse slot 114 and closely fits through an opening 122 in the cutting blade 98. The sides of the protrusion 120 of the blade holder 96 engage the sides of the opening 122 in the cutting blade 98 which is thereby held for movement with the blade holder 96. In the preferred embodiment, the blade holder 96 and the cutting blade 98 oscillate perpendicular to the forward direction. However, although the oscillation is perpendicular, the cutting edge 102 is preferably angled relative to the forward direction, as described above.

The blade holder 96 also includes a vertical slot 105 which is perpendicular to the width of the blade holder and perpendicular to the angled blade surface 104. The cutting head 94 has a back surface with a passage 140 opening thereto. The passage 140 communicates with the transverse slot 114 in the cutting head 94 and the vertical slot 138 in the blade holder 94. The passage 140 also is perpendicular to the transverse slot 114 and parallel to the blade surface 104.

Figs. 3 and 9 show the wedge-shaped wedge 100 which includes an upper surface 106 which is parallel to the angled cutting blade surface 104 (Fig. 7). The wedge 100 has an approximately triangular cross-section with a thinner portion facing forward toward the cutting edge 102 of the cutting blade 98. The wedge 100 has an angled top surface 106, as mentioned above, which supports the cutting blade 98 as it

oscillates with the blade holder 96. The cutting head 94 and the wedge 100 form a carriage for carrying and supporting the cutting blade 98.

The tip of the protrusion 120 (Fig. 8) in the blade holder 96 (Fig. 8) extends through the opening 122 in the cutting blade 98 and is received in a transverse recess 126 in an angled surface 106 of the wedge 100. The transverse recess 126 extends parallel to and substantially coextensive with the transverse slot 114 (Fig. 7) in the cutting head for receiving the blade holder 96 (Fig. 8).

The wedge 100 also includes a pair of protrusions 128 extending substantially perpendicular from the angled top surface 106. These protrusions 128 are adapted to be press fit into a pair of corresponding recesses 130 (Fig. 9) in the underside of the cutting head 94. The recesses 130 cooperate with the protrusions 128 to locate and hold the wedge 100 in place relative to the cutting head such that the upper angled surface 106 is substantially parallel to the angled blade surface 104 (Fig. 9) with the cutting blade 98 interposed therebetween. The wedge 100 locks the cutting blade 98 and the blade holder 96 in the cutting head 94 while allowing the cutting blade 98 and the blade holder 96 to oscillate. Although the nature of the fit should hold the wedge 100 in place, preferably a surgical adhesive or medical grade epoxy is used to ensure that the wedge 100 remains in place.

The thicker side of the wedge 100, the back end of the wedge, has a groove 132 extending approximately halfway across the width of the wedge 100 and a bore 134

extending from the deepest portion of the groove 132 and coaxial therewith through the remaining width of the wedge 100. The groove 132 and bore 134 are adapted to receive a T shaped pin 135 (Fig. 3) extending from an end of the axial shaft 64 (Fig. 1) opposite the sliding member 52 (Fig. 1).

Preferably, each part of the microkeratome 12 described above is composed of transparent materials, such as transparent plastics, to permit the surgeon to see what is happening during the operation. The only component which is not transparent is the cutting blade 98.

Returning to the connections between the cables 18 and 20 and the microkeratome 12, the axial shaft is connected to the wedge with a T pin and slot arrangement and the rotary cable is connected to the blade holder through an eccentric and a bayonet connection. The T shaped pin has a top crossing member which is rotatably coupled to a trunk member which is axially aligned with the axial shaft 64. The rotatable connection permits the axial shaft 64 and the trunk member to twist without transmitting a torque to the cutting assembly 74. Other types of connecting devices for connecting the axial shaft to the cutting assembly may be used, including but not limited to screws, bolts, rivets, adhesives, etc. Furthermore, the axial shaft may be connected to another part of the cutting assembly other than the wedge. For example, the axial shaft may be connected to the cutting head. However, preferably in whatever

connecting devices are used, the axial shaft 64 must be free to rotate relative to the connecting device, as explained above.

The axial shaft 64 runs within an axial cable 20 for moving the cutting assembly 74 and the fitting 146 on the axial cable 20 ensures that the axial shaft 64 moves the cutting head 94 relative to the suction platform 76 (see Fig. 1).

The rotary shaft 66 has a fitting with an eccentric on an end removed from the rotary motor 60 (Fig. 1) for rotation with the rotary shaft 66 (Fig. 1). The eccentric passes through the passage 140 in the cutting head 94 to engage the vertical slot 138 in the blade holder 96. The eccentric on the rotary shaft 18 (Fig. 1) is held against the cutting head 94 by a bayonet coupling which engages a pair of opposing pins 142 at an open end of the passage 140 in the cutting head 94. The bayonet coupling is held in place with friction and permits the rotary shaft 66 to rotate in either direction while retaining the fitting and the eccentric in a fixed position relative to the cutting head 94.

The rotary motor 60 produces a rotational motion in the rotary shaft 66 and the rotary shaft transmits the rotary motion through the rotary cable 18 to the fitting and the eccentric. The eccentric and the vertical slot 138 in the blade holder 96 cooperate to transform the rotary motion of the eccentric to a linear oscillating motion in the blade holder 96 and the cutting blade 98. The rotary shaft 66 preferably rotates at about twelve thousand five hundred revolutions per minute. Preferably the oscillating motion is perpendicular to the direction of motion of the cutting head on the suction platform,

however, the slots in the cutting head and wedge and/or the angle of the cutting edge may be varied relative to the direction of motion of the cutting head.

The rotational speed created by the rotary motor drives the oscillation of the cutting blade. The forward motion created by the axial motor drives the cutting assembly across the suction platform. The present invention permits the speeds of the rotary motor and the axial motor to be adjusted independently of each other. Thus different combinations of cutting blade oscillation speed and linear speed across the cornea can be achieved.

Naturally, the suction tube 16 and the axial and rotary cables 20 and 18, respectively, connect with the microkeratome 12 from directions that minimize or eliminate the chance that a cable or tube would cross the circular opening 84 in the suction platform 76 where the cutting is performed. Preferably, the suction tube 16 and the axial and rotary cables 20 and 18, respectively, are aligned along the cutting direction with the cutting assembly 74 interposed between the suction tube on one side and the cables 18 and 20 on the other.

In addition to all of the other components of the surgical system according to the present invention described above, the system 10 also includes a hand tool 150 (shown in Fig. 1). The hand tool 150 holds the axial and rotary cables 20 and 18, respectively, adjacent the microkeratome 12 to facilitate holding and supporting the cables during an operation. Preferably the hand tool 150 holds the rotary cable 20 at an angle such that

if the axial cable 18 is substantially straight, the rotary cable 20 will be substantially coaxial with the passage 140 in the cutting head 76 (see Fig. 7).

The axial shaft 64 translates the motion of the sliding member 52 (Fig. 1) to the cutting assembly 74 through the T shaped pin 135 and the groove 132 and bore 134 in the wedge 100. The protrusions or pins 128 in the upper surface of the wedge 128 transmit the force from the axial shaft 20 (Fig. 1) to the cutting assembly and push it across the top surface 80 (Fig. 5) of the suction platform 76 as directed by the platform guides 82 (Fig. 5) and rails 112 (Fig. 6).

In summary, the disposable microkeratome 12 includes a cutting assembly 74 and suction platform assembly 72 combination. The suction platform assembly 72 is seated on the cornea of an eye and is fixedly located thereon. The microkeratome 12 is operated by a control assembly 14 that directs the movement of the cutting assembly 74 across the suction platform assembly 72 through two specially designed flexible cables 18 and 20.

As will be described in greater detail below with respect to a preferred embodiment, the controller 28 in the control assembly 14 controls the axial motor 50, the rotary motor 60, and the suction pump 26. Based on the discussion herein, it will be readily apparent to one skilled in the art to weigh the advantages and disadvantages of different control mechanisms and to select one suitable to carry out the present invention. The control assembly 14 can include any of numerous technologies

available today, including but not limited to logic gate controllers, switches and relays, and software programming. Accordingly, one skilled in the art would appreciate that the scope of the present invention is intended to include all such suitable control mechanisms.

The operation of the opthalmic surgical system 10 according to the present invention will be described below with reference to Figs. 1 and 11-13. A new microkeratome 12 is connected to the control assembly 14 through the suction line 16 and the rotary and axial control cables 18 and 20, respectively, as described above.

As shown in Fig. 13, the system is powered up via an ON/OFF switch 30 (also schematically illustrated in Fig. 1) or the like connected to a power source 200 through a transformer 202. The microkeratome 12 is placed over an eye to seat the suction chamber 86 on the eye with a cornea protruding through the opening 84 in the top surface 80 of the suction platform 76. The suction is turned on through the suction on/off switch 206 which activates the suction pump 26 through a solid state suction relay 208 to apply suction, thereby creating a partial vacuum in the suction chamber 86 for retaining the eye in position relative to a suction platform 76. In other words, when the microkeratome 12 is placed over the eye such that the cornea protrudes from the suction chamber 86 through the opening 84 in the suction platform 76, the suction pump 26 secures the eye in position for surgery. The microkeratome 12 can be completely connected to the control assembly 14 before it is placed on the eye. The

connected microkeratome 12 is simply placed on the eye, suction is applied, and the surgeon can begin the operation.

Before the operation is started, however, the surgeon should select the desired flap length with the flap length adjustment selector 34 described above. The flap length adjustment selector 34 tells the controller 28 how far or how long to drive the axial motor 50 and thus drive the cutting assembly 74 across the opening 84 in the suction platform 76 to cut the cornea.

Once the surgeon is ready to begin, the two position foot pedal 32 is moved to a forward position and is held there, tripping reverse switch 204. The foot pedal 32 is biased to a neutral position between a reverse position and the forward position. Reverse switch 204 is activated and the axial motor 50 runs in a reverse or backward direction to move the slide member 52, which is connected to the cutting assembly 74 (Fig. 3) through the axial and rotary shafts 20 and 18, respectively, in a reverse or backwards direction. The rotary motor 60 is not activated during this step and the cutting blade does not oscillate. The slide member 52 continues to move in a reverse direction until an initial position microswitch is tripped at an initial position (see Figs. 1 and 11). Tripping the initial position switch 68 automatically stops the axial motor and causes a first relay to energize. The first relay is linked to a direction switch which moves from a reverse position to a forward position when the first relay is energized. The axial motor automatically begins to run in a forward direction. Simultaneously, the

rotary motor is activated as well. The rotary motor thus causes the cutting blade to oscillate and the axial motor causes the cutting assembly to move forward in the cutting direction.

Still holding the foot pedal in the forward position, the slide member and the axial and rotary shafts advance, leading to the advance of the cutting assembly and the transverse oscillation of the cutting blade until the hinge position microswitch is tripped by the slide member, and the cut in the cornea that forms the flap is complete. Tripping the hinge position microswitch stops both motors automatically. If the foot pedal is released at any time, both motors stop and the procedure must begin again from the start, with the cutting assembly returning to the initial position before cutting again.

To complete the operation, the surgeon depresses the foot pedal to the reverse position and the cutting assembly moves in a reverse direction opposite the forward direction until the slide member trips the initial position switch and comes to a stop. As a result of the combination of switches tripped in sequence, this does not lead to the automatic forward cutting motion that started the operation.

In order to secure an accurate operation and to avoid injury to the eye, the suction pump 26 must operate at all times while the flap is being cut. As a safety measure, the controller 28 automatically shuts off the rotary and axial motors 60 and 50, respectively, whenever suction is lost or falls below a predetermined value, as determined by a pressure sensor switch 210. Furthermore, after suction is lost, the

pressure sensor switch 210 is tripped, and the axial and rotary motors 50 and 60, respectively, are shut off, the only available operation is to depress the foot pedal to the reverse position. As explained above, the axial motor 50 then runs in reverse to return the slide 52 and the cutting head 94 to the initial position. As mentioned above, the rotary motor 60 does not operate when the axial motor 52 is running in reverse.

Although the invention has been shown and described with respect to a certain preferred embodiment or embodiments, equivalent alterations and modifications will occur to others skilled in the art upon the reading and understanding of this specification and the annexed drawings. In particular regard to the various functions performed by the above described integers (components, assemblies, devices, compositions, etc.), the terms (including a reference to a "means") used to describe such integers are intended to correspond, unless otherwise indicated, to any integer which performs the specified function of the described integer (i.e., that is functionally equivalent), even though not structurally equivalent to the disclosed structure which performs the function in the herein illustrated exemplary embodiment or embodiments of the invention. In addition, while a particular feature of the invention may have been described above with respect to only one of several illustrated embodiments, such feature may be combined with one or more other features of the other embodiments, as may be desired and advantageous for any given or particular application.

CLAIMS

What is claimed is:

1. A keratomileusis opthalmic surgerical system comprising:

a microkeratome for cutting a cornea of an eye including

a suction platform having a top surface, a suction chamber opening to a bottom side, and an opening extending from the top surface to the suction chamber, the suction chamber being adapted to be seated on the eye such that at least a portion of the cornea passes through the opening and protrudes above the top surface of the suction platform, and

a cutting assembly including a carriage and a cutting blade carried in the carriage, the carriage being guided for movement in a linear cutting direction for moving the cutting blade across the opening in the suction platform, and

a control assembly for automatically controlling the microkeratome, the control assembly including

an axial drive for generating linear movement, the axial drive being connected to the microkeratome to impart linear movement to the cutting assembly relative to the suction platform in a cutting direction,

a rotary drive for generating rotational movement, the rotary drive being connected to the microkeratome to impart an oscillating movement to the cutting blade transverse to the cutting direction,

a suction device for generating a partial vacuum, the suction device being connected to the microkeratome for generating a partial vacuum in the suction chamber to maintain a position of the suction platform relative to the eye, and

a controller for independently controlling the axial drive and the rotary drive.

2. A system as set forth in claim 1, wherein substantially all of the microkeratome is formed of a substantially transparent material.

3. A system as set forth in claim 1, wherein the control assembly includes a drive assembly, the drive assembly including the axial drive, a slide member connected to the axial drive, and the rotary drive;

wherein the slide member is moved through a range of linear motion by the axial drive;

wherein the rotary drive is mounted on the slide member for movement therewith;

wherein the axial drive is connected to the microkeratome through an axial shaft connected to the slide member; and

wherein the rotary drive is connected to the microkeratome through a rotary shaft.

4. A system as set forth in claim 1, wherein the suction device includes a suction pump which is connected to the suction platform of the microkeratome through a suction tube.

5. A system as set forth in claim 3, wherein the cutting assembly includes a cutting head, a blade holder, the cutting blade and a wedge;

wherein the cutting head has an angled bottom surface with a transverse slot opening thereto, at least one recess therein and a back surface with a passage extending therethrough to the transverse slot;

wherein the blade holder has a protrusion on a bottom end thereof and a vertical slot in a side of the blade holder, the blade holder being received in the transverse slot for transverse movement therein with the protrusion extending below the bottom surface of the cutting head;

wherein the cutting blade has a cutting edge and a central opening, the protrusion on the blade holder engaging the central opening in the cutting blade for transverse movement therewith;

wherein the wedge has an angled top surface substantially parallel to the angled bottom surface of the cutting head with at least one protrusion extending therefrom to engage the at least one recess in the cutting head and hold the wedge against the cutting head and thereby retain the blade holder and blade;

wherein the rotary shaft has an eccentric on an end thereof which communicates with the vertical slot in the blade holder and cooperates therewith to convert the rotational motion of the rotary shaft into a transverse oscillating motion of the cutting blade; and

wherein the axial shaft is connected to the back side of the wedge to move the cutting assembly across the suction platform.

6. The system as set forth in claim 5, wherein the transverse slot is perpendicular to the angled bottom surface of the cutting head and the passage through the cutting head is parallel to the angled bottom surface.

7. The system as set forth in claim 3, wherein the rotary shaft is connected to the cutting assembly with a bayonet coupling.

8. The system as set forth in claim 3, further comprising an axial retaining clip mounted on the suction platform, wherein a fitting is held by the axial retaining clip and the axial shaft passes through the fitting and is attached to the cutting assembly.

9. The system as set forth in claim 8, wherein the axial shaft is connected to the cutting assembly with a T-pin that engages a slot in the back side of the wedge.

10. A method for keratomileusis opthalmic surgery providing independent control of linear movement of a cutting blade in a cutting direction and oscillating movement in a transverse direction, comprising the steps of:

linearly advancing a cutting blade from an initial position in the cutting direction while simultaneously oscillating the blade in a direction transverse the cutting direction;

automatically stopping the linear advance and transverse oscillation of the blade at a hinge position which is a predetermined distance from the initial position; and

linearly retracting the blade to the initial position without imparting transverse oscillation to the blade.

11. A method as set forth in claim 10, further comprising the steps of:

connecting an axial drive to the cutting assembly to advance and retract the cutting blade;

connecting a rotary drive to a cutting assembly to oscillate the cutting blade;

applying a microkeratome containing the cutting assembly to an eye; and

retaining the position of the cutting assembly relative to the eye with a suction device creating a partial vacuum between the microkeratome and the eye.

12. A method as set forth in claim 10, wherein the stopping step includes stopping the linear advance of the blade at an end position which is a less than three quarters of a distance across the eye.

13. A method as set forth in claim 11, further comprising the steps of stopping the axial drive and the rotary drive when a suction pressure is reduced below a predetermined value.

14. A keratomileusis opthalmic surgerical microkeratome comprising:

a suction platform having a top surface, a suction chamber opening to a bottom side, and an opening extending from the top surface to the suction chamber, the suction chamber being adapted to be seated on the eye such that at least a portion of the cornea passes through the opening and protrudes above the top surface of the suction platform, and

a cutting assembly including a carriage and a cutting blade carried in the carriage, the carriage being guided for movement in a linear cutting direction for moving the cutting blade across the opening in the suction platform, the cutting blade being movable in an oscillating motion transverse to the cutting direction,

wherein the carriage is movable in the cutting direction without imparting the oscillating motion to the cutting blade.

15. A microkeratome as set forth in claim 14, wherein substantially all of the microkeratome is formed of a substantially transparent material.

16. A microkeratome as set forth in claim 14, wherein the cutting assembly includes:

a cutting head having an angled bottom surface with a transverse slot opening thereto, at least one recess in the angled bottom surface and a back surface with a passage extending therethrough to communicate with the transverse slot;

a blade holder having a protrusion on a bottom end thereof and a vertical slot in a side of the blade holder, the blade holder being received in the transverse slot for transverse movement therein with the protrusion extending below the bottom surface of the cutting head;

the cutting blade having a cutting edge and a central opening, the protrusion on the blade holder engaging the central opening in the cutting blade for transverse movement therewith;

a wedge having an angled top surface substantially parallel to the angled bottom surface of the cutting head with at least one protrusion extending therefrom to engage the at least one recess in the cutting head and hold the wedge against the cutting head and thereby retain the blade holder and blade;

wherein the vertical slot in the blade holder communicates with the passage in the cutting head for receiving an eccentric on an end of a rotating shaft to convert the rotational motion into a transverse oscillating motion of the blade holder and the cutting blade; and

wherein the cutting assembly is adapted to receive a connection to an axial shaft for moving the cutting assembly across the suction platform.

17. The microkeratome as set forth in claim 16, wherein the transverse slot is perpendicular to the angled bottom surface of the cutting head and the passage through the cutting head is parallel to the angled bottom surface.

18. The microkeratome as set forth in claim 16, wherein the cutting assembly is adapted to receive a bayonet coupling adjacent the passage through the cutting head to retain a rotary shaft therein.

19. The microkeratome as set forth in claim 16, further comprising an axial retaining clip mounted on the suction platform for retaining a fitting which permits an axial shaft to pass through the fitting to attach to the cutting assembly for moving the cutting assembly linearly relative to the suction platform.

20. The microkeratome as set forth in claim 19, wherein a back side of the wedge is adapted to receive a T-pin on a distal end of the axial shaft.

21. The microkeratome as set forth in claim 16, wherein the suction platform includes at least one guide for retaining the cutting assembly adjacent the suction platform and for directing the motion of the cutting assembly across the suction platform; and

wherein the suction chamber forms a hollow cylinder aligned with the opening in the suction platform for passage of a portion of an eye therethrough, and

wherein a suction pipe is attached to the suction platform in line with the direction of motion of the cutting assembly, the suction pipe adapted to connect the suction chamber with a suction device.

* * *

ABSTRACT

An opthalmic surgical system and method including a microkeratome and a control assembly. The control assembly includes an axial drive for generating linear movement which is connected to the microkeratome to impart linear movement to a cutting assembly relative to a suction platform which maintains the microkeratome on the eye via a suction device. The control assembly also includes a rotary drive for generating rotational movement which is connected to the microkeratome to impart an oscillating movement to the cutting blade. The control assembly includes a controller for automatically and independently controlling the axial drive and the rotary drive.

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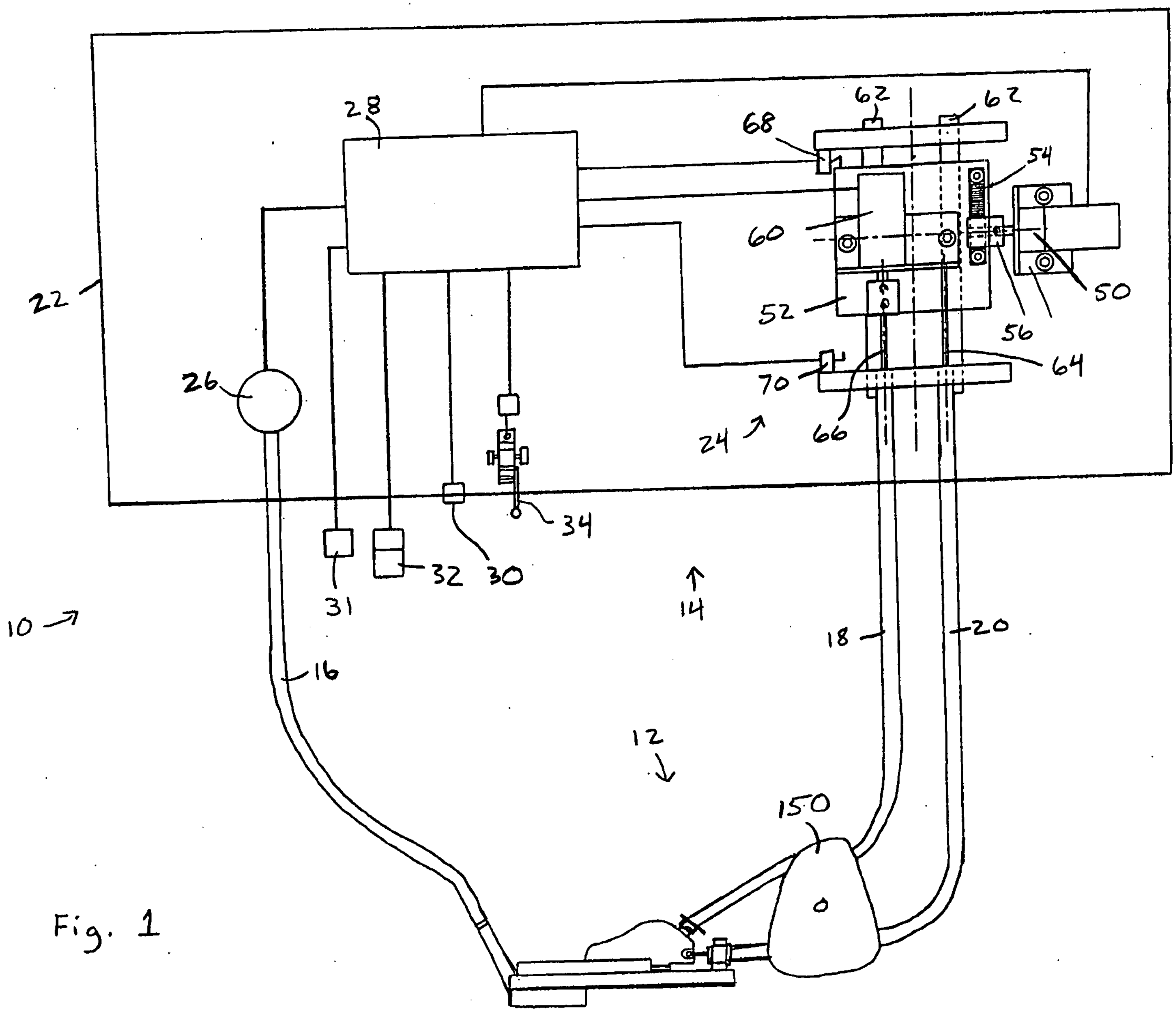
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Fig. 1

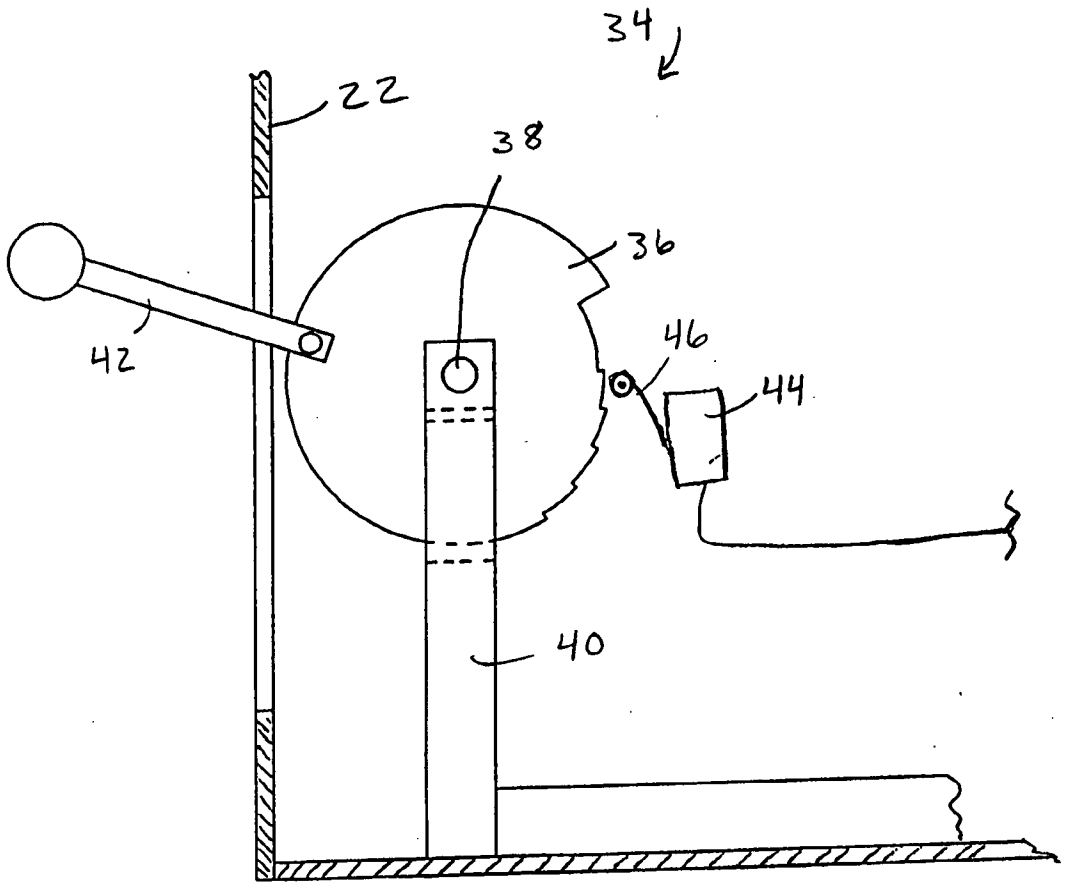


Fig. 2

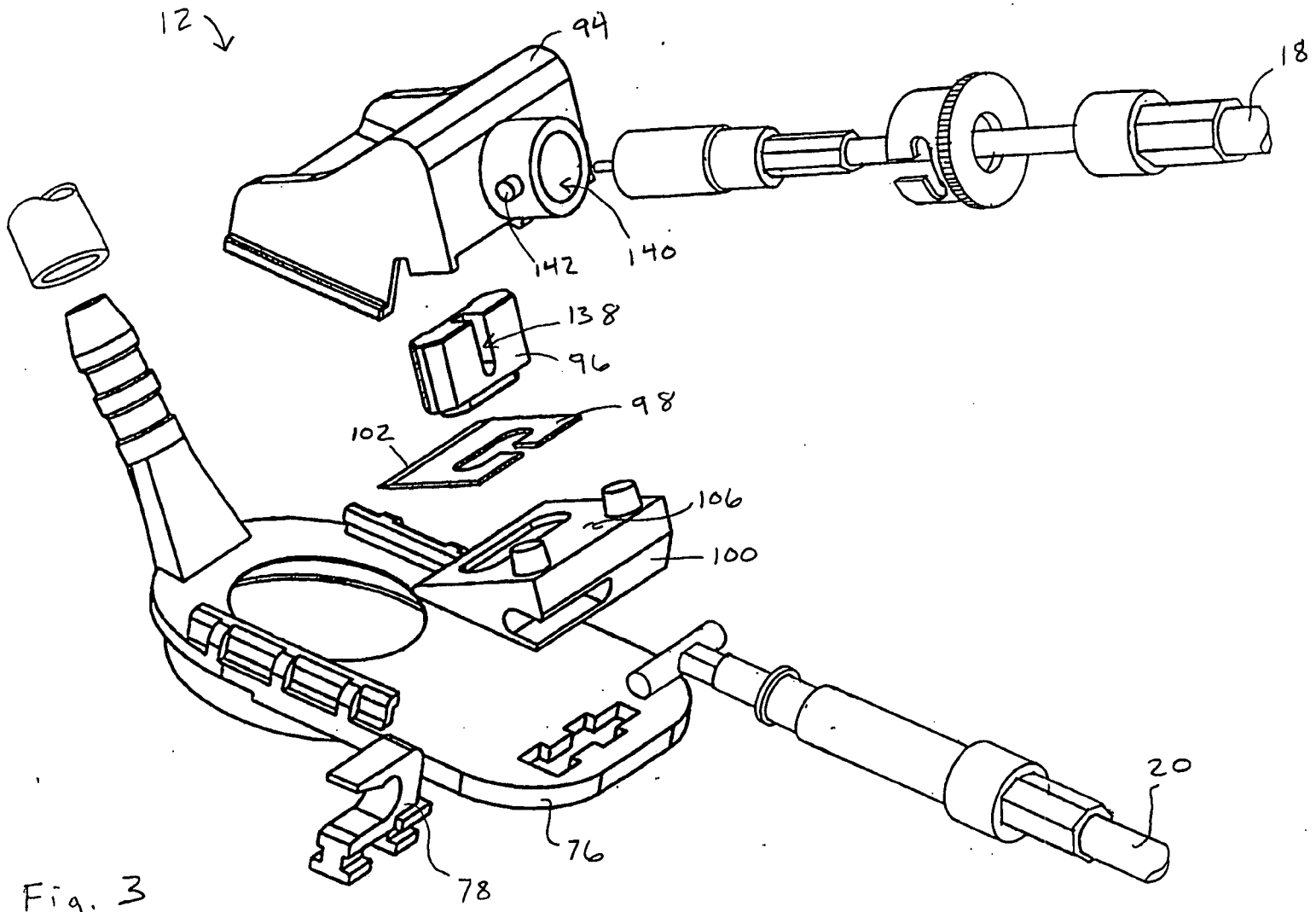


Fig. 3

Fig 4.

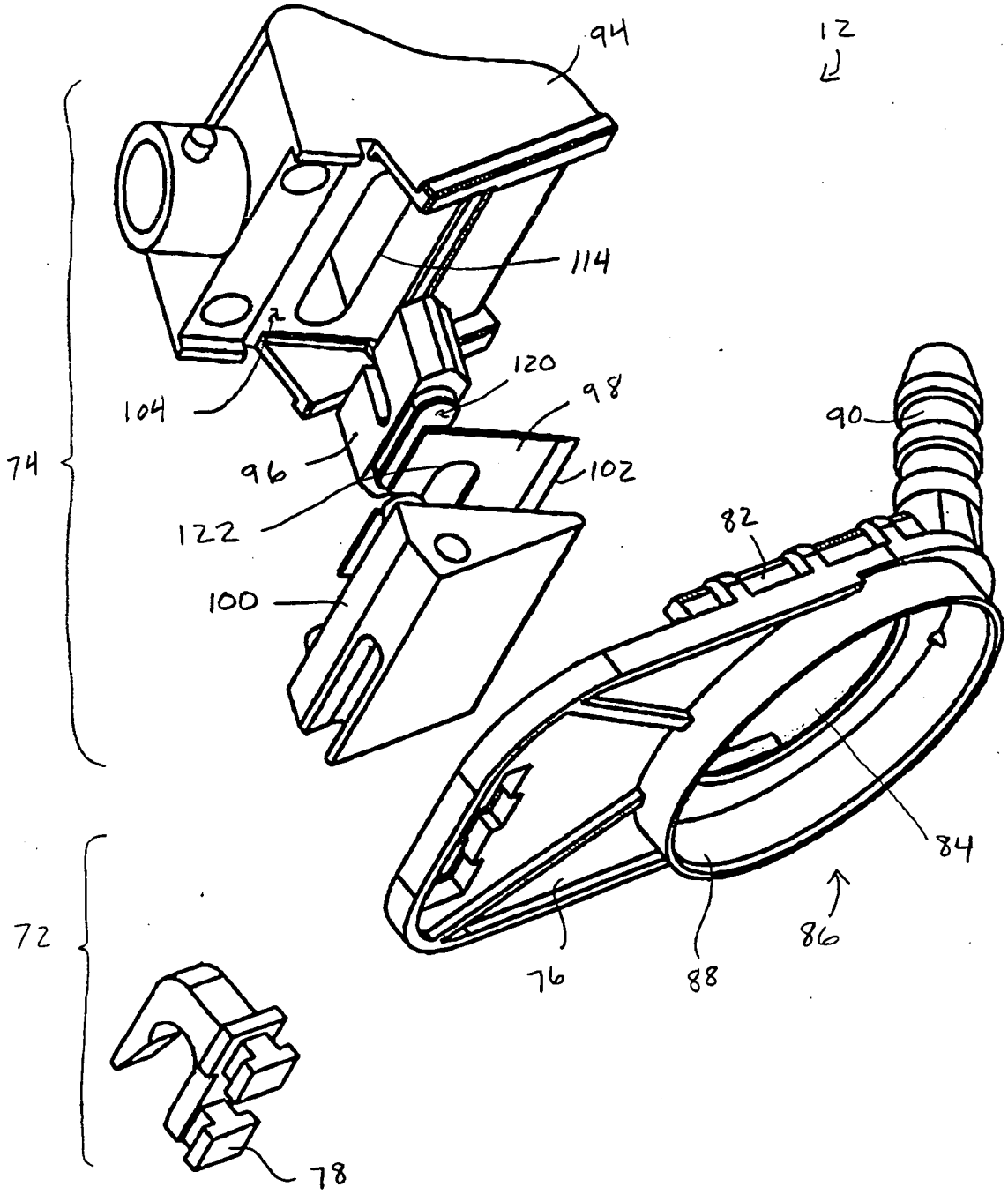
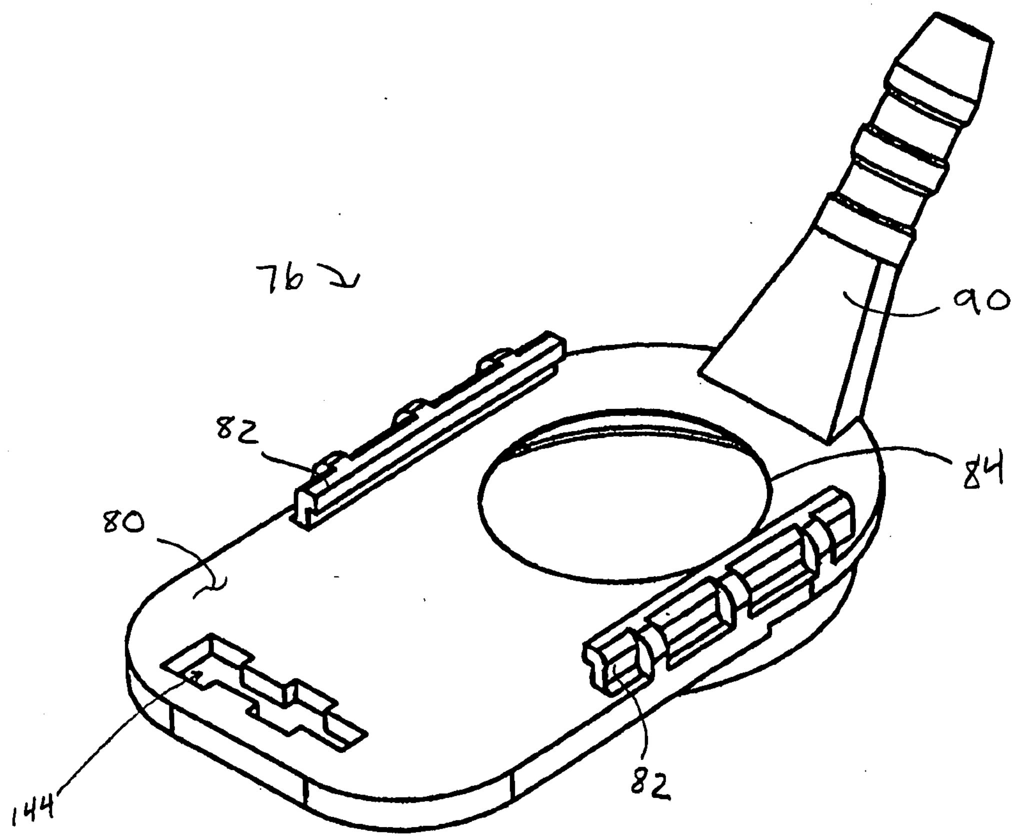


Fig. 5



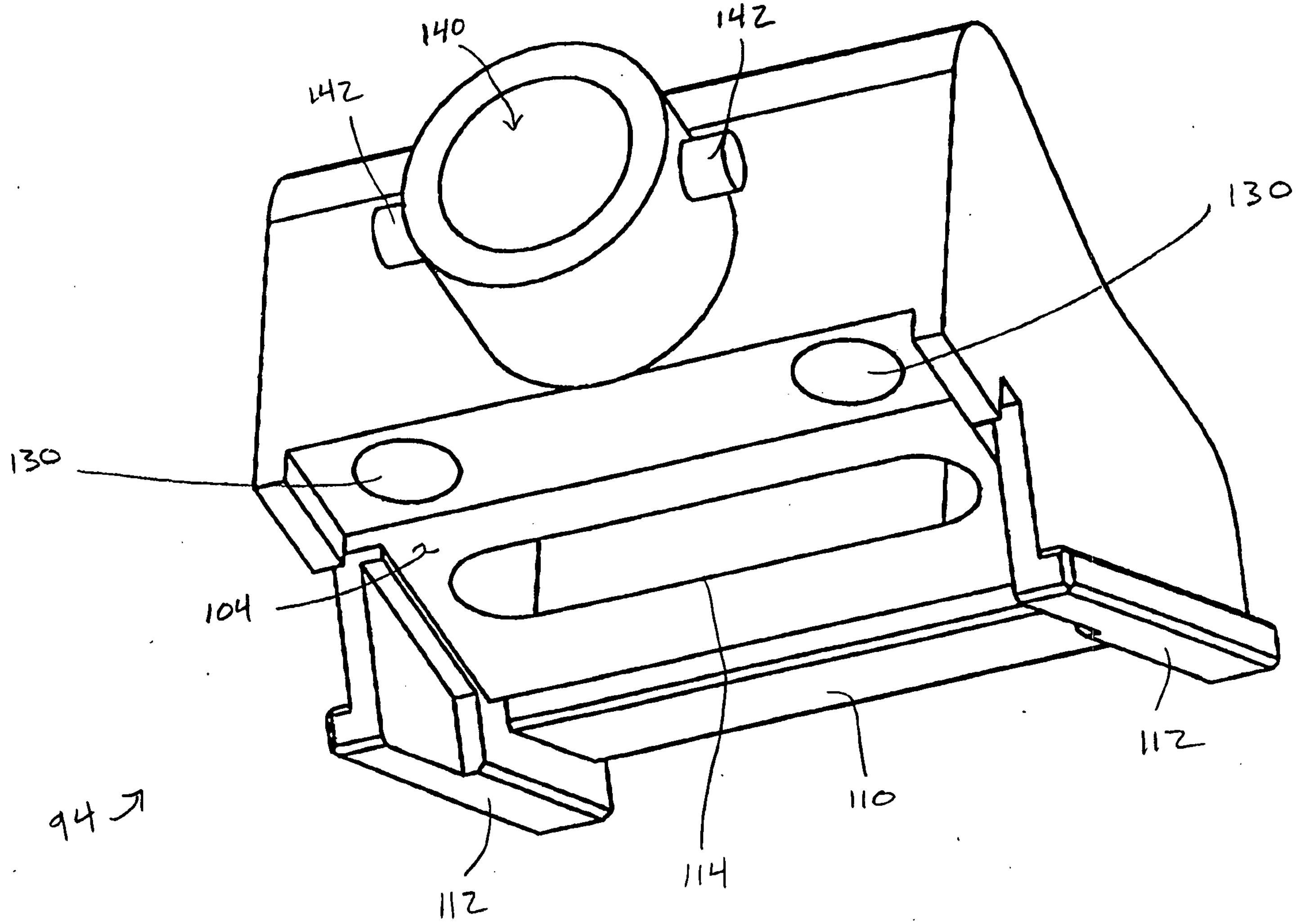
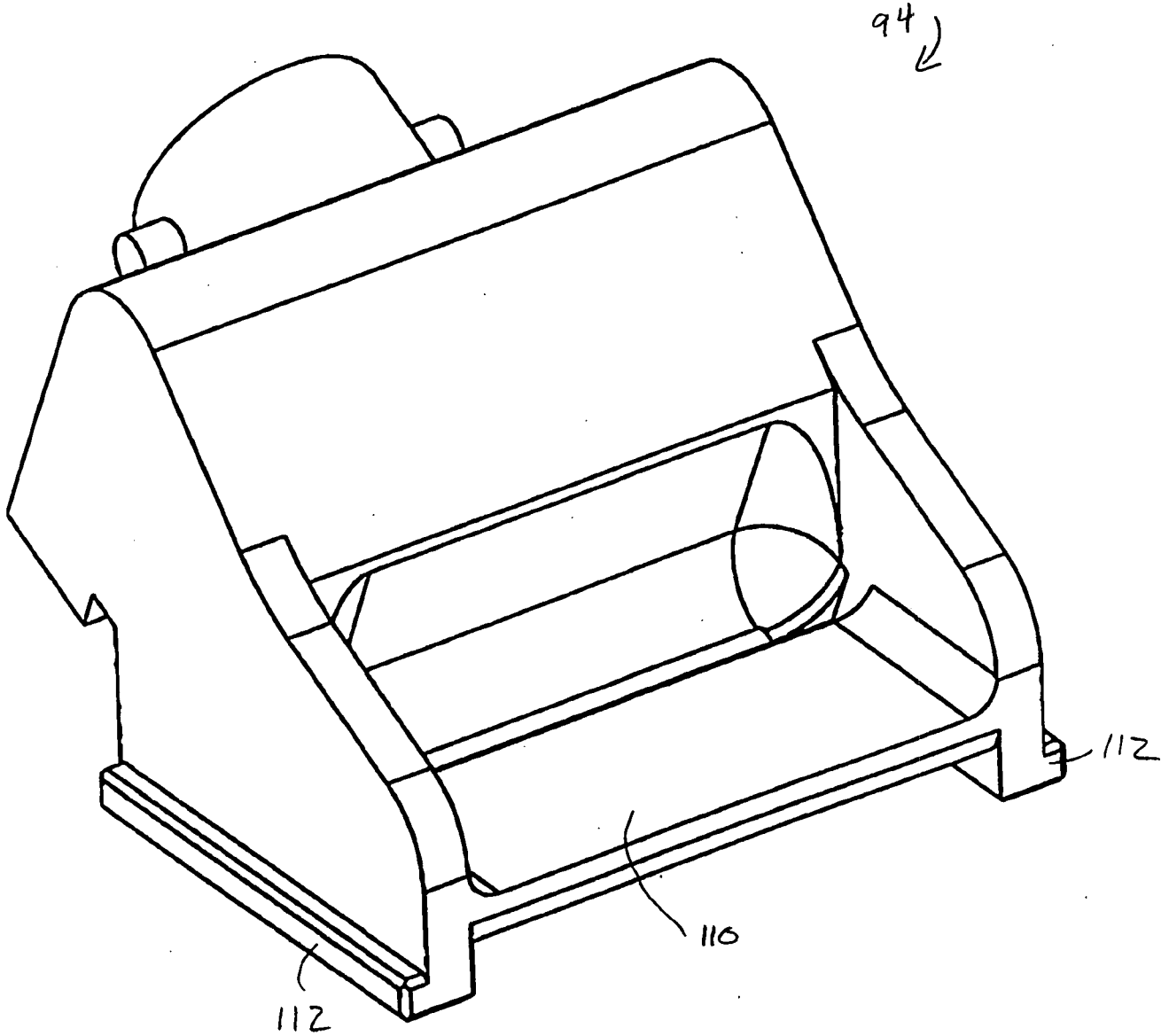


Fig. 7

Fig 6



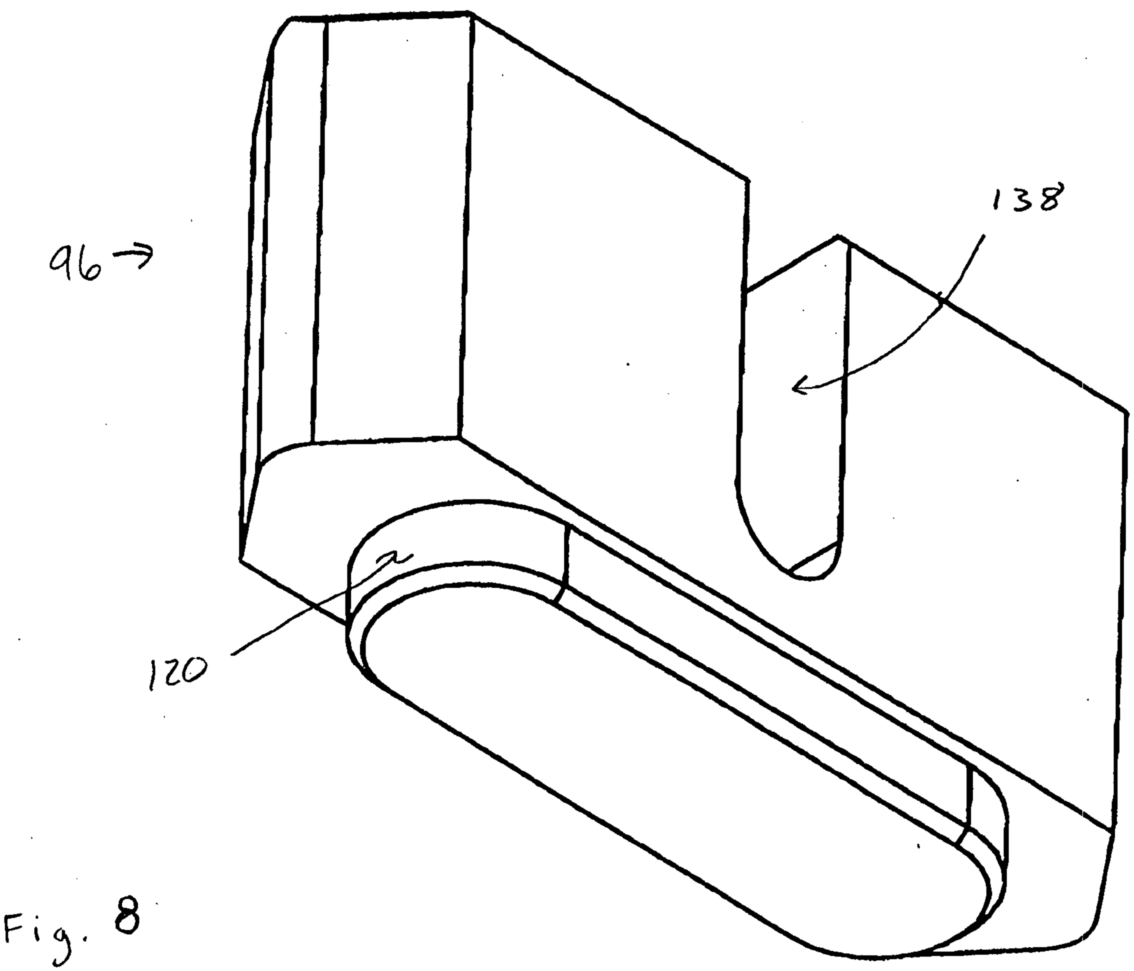


Fig. 8

Fig. 9

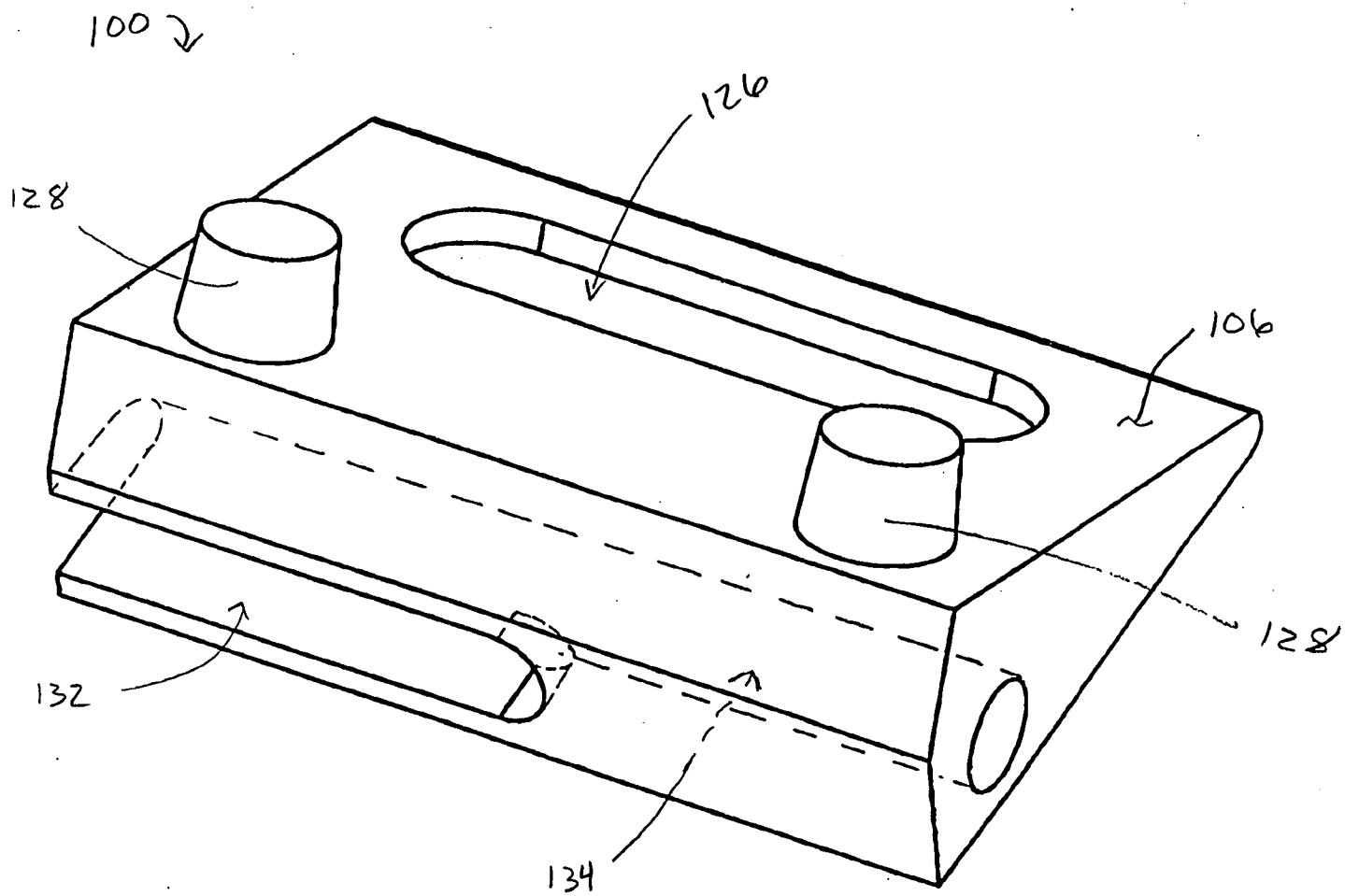


Fig. 10

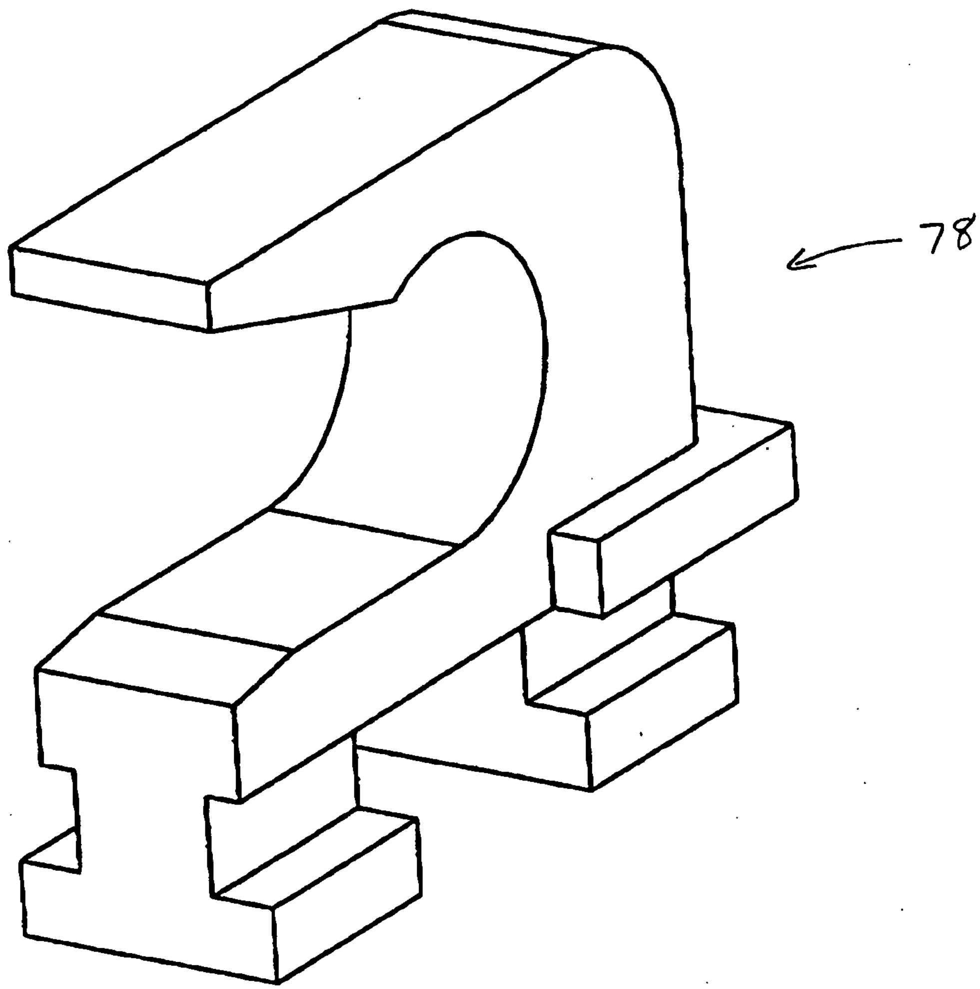


Fig. 11

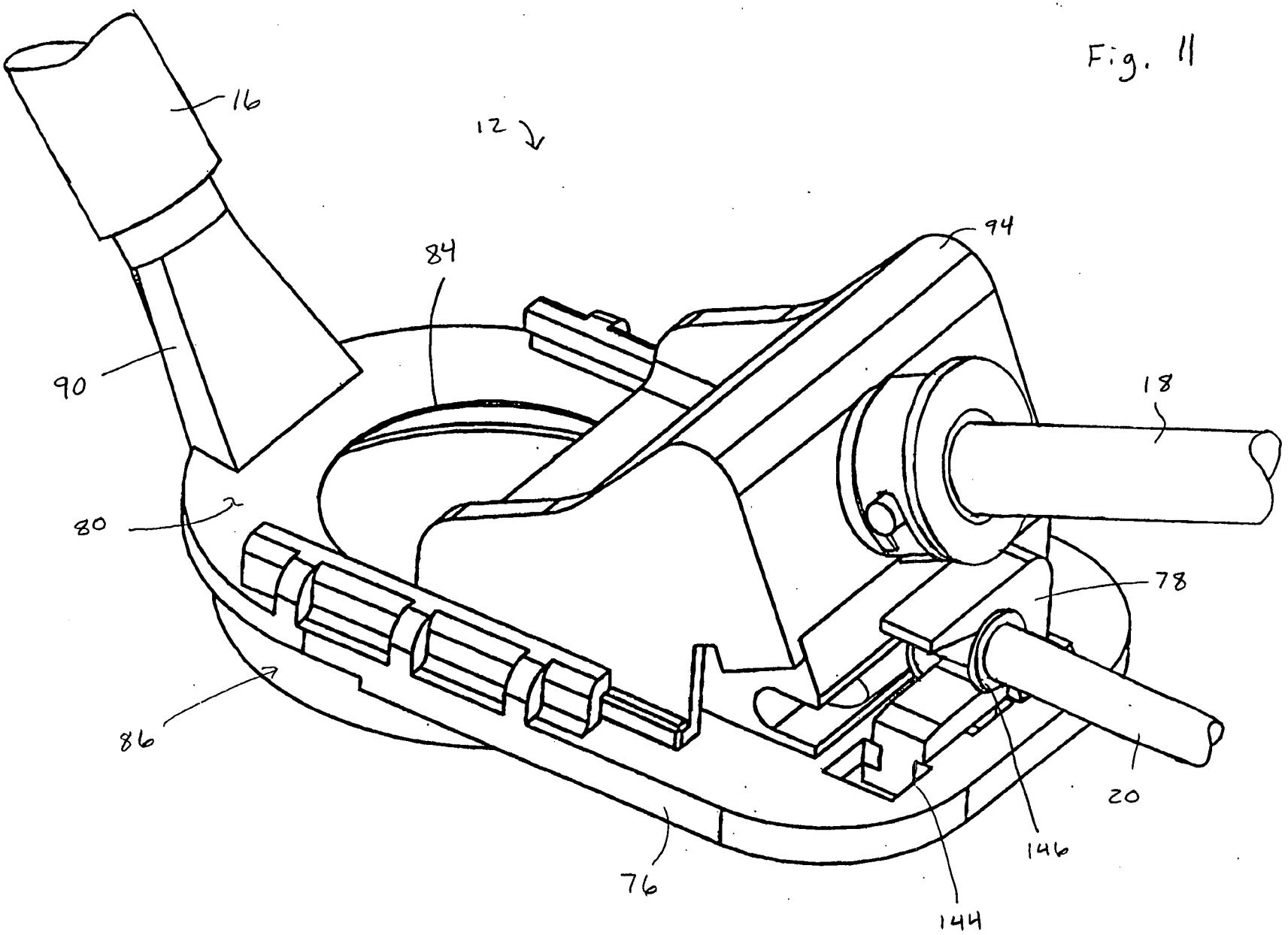


Fig. 12

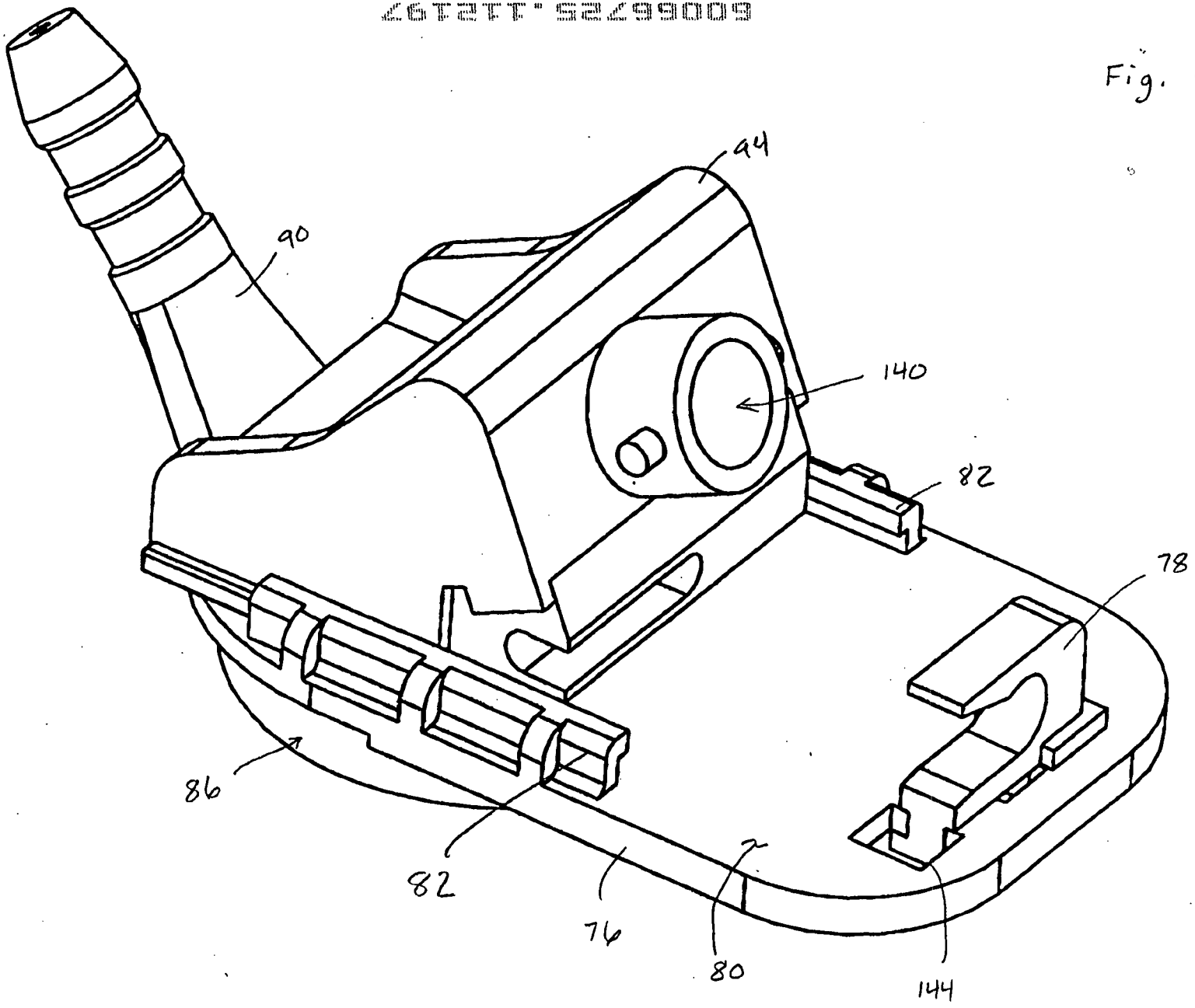


Fig. 13